

CLAIMS

1. 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methyl
ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride characterized by a
5 melting range of 180-200°C determined by Differential Scanning Calorimetry
and a X-ray powder diffraction pattern having *inter alia* one or more of the
following characteristic peaks: 12.2; 13.6; 16.3; 18.0; 18.2; 19.2; 21.4; 21.9;
22.8; 23.5; 24.2; 24.9; 26.6; 28.5; 29.4; 29.9; and 33.9 ± 0.2 degrees /2 theta.
2. 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methyl
10 ethyl]amino] ethyl]-2(1H)-quinolinone monohydrochloride of claim 1
characterized by a melting range of 185-195°C determined by Differential
Scanning Calorimetry.
3. 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methyl
ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride of claims 1-2
15 having a crystalline degree expressed as weight % of the crystalline compound
with respect to the total weight of the compound of at least 90%.
4. 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methyl
ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride of claims 1-3
having a crystalline degree expressed as weight % of the crystalline compound
20 with respect to the total weight of the compound of at least 93%.
5. 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methyl
ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride of claims 1-4
having a crystalline degree expressed as weight % of the crystalline compound
with respect to the total weight of the compound of at least 95%.
- 25 6. A process for the preparation of a compound as claimed in claims 1-5
comprising crystallising or re-crystallising the compound from an aqueous
ethanol solution added with diisopropyl ether wherein the aqueous ethanol
solution is concentrated to a volume comprised between 1/2 and 1/3 of the

initial volume and the addition of the diisopropyl ether is performed in at least 5 minutes.

7. A process according to claim 6 further comprising the step of re-crystallization from a protic solvent comprising ethanol, isopropanol or their
5 aqueous mixtures.